Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial)

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Intracervical Foley catheter for induction of labour

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Labour is induced in about 20% of pregnant women in high-income countries, making it one of the most frequently done obstetric interventions.[1,2] Induction is commonly offered to women at 41 weeks' gestation or greater, to reduce the risk of perinatal death.[3] Induction is also indicated in suspected maternal or fetal compromise, such as pregnancy-induced hypertension at term, for which delivery is likely to improve maternal or fetal health.[4]

The optimum method of induction of labour is uncertain. Vaginal or intracervical prostaglandins are used in the UK and USA. Alternatives include mechanical methods, such as forewater amniotomy, laminaria tents, or an intracervical Foley catheter; all these methods probably stimulate endogenous prostaglandin production, thus ripening the cervix. Externally administered prostaglandins are effective at cervical ripening and hastening delivery, but increase the risk of uterine hyperstimulation with fetal heart rate changes.[5] In nulliparous women or women with previous vaginal deliveries, there is no evidence that prostaglandin-induced uterine hyperstimulation is associated with substantial harm, since prostaglandins do not increase the risk of caesarean section or neonatal unit admission.[5] However, in women with a previous caesarean section, induction with prostaglandins is associated with uterine rupture.[6] The absolute risk is small, but the potential for perinatal death leads to caution about use of prostaglandins in this situation.[7,8]

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When labour onset occurs physiologically, the cervix ripens before myometrial contractions start. A major drawback of administered prostaglandins is that they affect both cervical ripening and contractions simultaneously. Contractions occurring before the cervix is ripe are not effective in progressing labour and merely restrict blood flow to the fetus. We and others have proposed that the ideal strategy for induction would be administration of a cervical ripening agent before stimulation of contractions,[9,10] which would decrease the need for fetal monitoring during ripening (enabling outpatient use) and reduce the risk of uterine rupture. Although nitric oxide donors induce cervical ripening without inducing uterine contractions,[11] they do not hasten the onset of delivery or reduce the need for additional agents when used for induction of labour.[12,13] By contrast, in *The Lancet* Marta Jozwiak and colleagues[14] show that intracervical placement of a Foley catheter induces cervical ripening without inducing uterine contractions and is as successful as prostaglandin for induction of labour, according to the number of failed inductions and caesarean section rates.

The researchers randomly assigned 824 women to either induction of labour with a Foley catheter or prostaglandin E2 (up to 3 mg). If cervical ripening had not been achieved by 48 h, the woman rested for a day and then had a single repeat treatment. Once the cervix had ripened, induction of labour was continued with forewater amniotomy and oxytocin infusion. The rate of caesarean section (the primary outcome) was much the same in both groups (93 [23%] for Foley catheter *vs* 82 [20%]

for prostaglandins, relative risk 1·13, 95% CI 0·87–1·47, p=0·38). Although the induction-to-delivery interval and rates of caesarean section for failure to progress in the first stage of labour both increased, women in the Foley catheter group had reduced rates of both operative delivery for fetal distress and neonatal unit admission. In a meta-analysis, the investigators show that Foley catheter induction is similar to prostaglandin induction for caesarean section rate but significantly reduces rates of hyperstimulation (odds ratio 0·44, 95% CI 0·21–0·91) and postpartum haemorrhage (0·60, 0·37–0·95). Although women's views of the Foley catheter were not formally assessed, 74% of eligible women approached agreed to participate in the trial, and less than 0·5% declined when allocated to the Foley catheter, implying high pretreatment acceptability.

These data suggest that Foley catheter induction of labour is effective and should be considered for use in clinical practice. Some authorities caution against mechanical methods of cervical ripening or induction of labour because of the perceived increased risk of infection.[7] Jozwiak and colleagues report no evidence of increased infection for either mothers or babies, and these data should prompt a revision of the recommendation that "mechanical procedures (balloon catheters and laminaria tents) should not be used routinely for induction of labour".[7] The low cost of the Foley catheter could make it particularly useful in resource-limited settings.

Jozwiak and co-workers' study makes an important contribution. The nature of Foley catheter treatment means that it would not have been easy to conceal treatment allocation; however, despite the open-label design, the randomisation procedure was sufficiently robust to prevent treatment allocation bias. Important questions remain about the design of trials to test interventions for labour induction. The Cochrane collaboration suggests five potential primary outcomes for induction agents: vaginal delivery not being achieved within a specified time, caesarean section, uterine hyperstimulation with fetal heart rate changes, serious neonatal morbidity or mortality, and serious maternal morbidity or mortality.[15] In practice one primary outcome is often used, commonly (as here) caesarean section. By this measure, the Foley catheter was no better than prostaglandin. However, the reduced risk of hyperstimulation with the Foley catheter (a secondary outcome of Jozwiak and co-workers' study) is likely to be attractive to pregnant women (particularly those with a previous caesarean section) and clinicians. Although women with a previous caesarean section were excluded from Jozwiak and colleagues' study, a Foley catheter could be the ideal induction agent in this situation, and should be assessed further in randomised trials. If such trials are to be done, the avoidance of maternal and neonatal mortality and morbidity are arguably as important as speed and avoidance of caesarean section, and warrant inclusion as primary outcomes.

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JEN has received fees for acting as a consultant for Preglem, and is a member of an advisory board (unpaid) for Hologic. SS declares that she has no conflicts of interest.

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